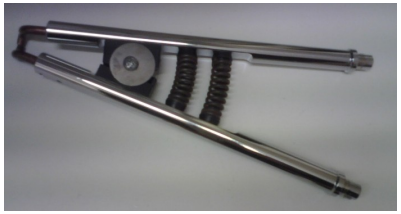
USER'S MANUAL
- PEWD -

"Intra-oral pliers for EWD welder"



Product identification

This manual was edited referring to the following devices:

Name: PEWD

Code: PAPINEWD001.1

Accessories

Item	Code
COPPER ELETTRODES	CEELTEWD6090AAA
PLIERS CONNECTING CABLES	PACAVEWD001.1

Manufacturer's identification

The manufacturer responsible for this product is:

Swiss & Wegman s.r.l.

Via Svezia, 8

Ponte San Nicolò (PD)

Italy

Scope of use

PEWD is a medical device specifically designed for the odontoiatric practice.

It is allowed to be used only with EWD welding equipment for which it has been purposely designed.

For further information about EWD intra-oral welder, please see EWD user's manual.

The intra-oral welding exploits the Joule effect to produce the heat necessary to fuse titanium in order to achieve high quality welding directly within the oral cavity.

The manufacturer is not responsible for any direct or indirect effect due to misuse of the device. Such undesired effects remain under the direct responsibility of the person who makes the intervention.

The user is invited to follow such instructions:

- The system must be installed and used according to the instructions given in this handbook, taking in special account those concerning safety;
- Any operation of modification, calibration and maintenance must be carried out by qualified staff authorized by the manufacturer;
- The electrical system to which the device is intended must be in compliance with both IEC requirements and all local rules. The system must be connected to ground.
- The manufacturer, the installer and the importer are responsible for safety, liability and efficiency of the device only if all the above-mentioned conditions are fulfilled.
- The manufacturer makes it available, on written request, the electric schemes and the test instructions for those parts of the system that are considered reparable in order that qualified staff authorized by the manufacturer could repair or test the device.

Application field

PEWD is a medical item intended for dental use as EWD accessory and enabling the clinician to transfer energy, in the form of electric power that coverts into heat, to two joints to be welded within the oral cavity.

PEWD has no therapeutic and/or diagnostical effect. It is a surgical device to be used in dental implant surgery.

PEWD application field is dental surgery.

PEWD is a medical device designed to be used in dental clinics or in health structures, whether hospitals or not, only by specialized medical staff.

Principle of action

As for the priciple of action please refer to EWD user's manual, being ***PEWD*** an EWD accessory.

Contraindications

PEWD enables to produce elevate current pulses and, as a consequence, remarkable electromagnetic fields. However, it is suitable for use in any medical or surgical context: its limits of emission widely comply with the standards imposed by regulations on electromagnetic compatibility for medical devices. Anyway, not having enough information about it, it is advised not to use *EWD* in presence of patients or operators carriers of pace-makers, implanted defibrillators or other electronical devices for life maintenance.

The electrodes and the intra-oral pliers are made of materials usually well tolerated by most people, but it cannot be excluded that some subjects may be allergic to such materials.

Such metals are: Brass, Nickel, Steel AISS 316, Copper, Chrome.

The patient gets in touch with only few parts of the handpiece and for a short time.Therefore, according to the case, the clinician will decide whether to use the device or not upon consideration of the secondary effects, which must be tolerable and lesser than the benefits.

Side effects

A misuse of the device can bring about unwanted side-effects, sometimes dangerous.

The main side effect to bear in mind is the risk to burn soft tissues near the weld site within the oral cavity.

This device has been designed to minimize the risk of side effects. In any case, undestanding such risks and using ***PEWD*** properly prevent the occurance of such effects.

The power discharge loop can only take place within the circuit constituted of the welding device, the cables, the pliers and the joints to be welded. Anyway, during welding process the absence of other conductors within the oral cavity is recommended to avoid the occurance of unexpected discharge loops.

The heat engendered during the welding process remains confined within the welding core and the increase of temperature along the rest of the metal is unimportant. In spite of this, it is advised that patients avoid to lean their tongue on the metal joints to be welded.

The danger of sparks formation in the welding phase is significantly reduced thanks to the pliers pressure strenght which prevents the generation of empty spaces during the discharge phase. Indeed, it occurs that, because of local metal fusion, a reduction of metal thickness takes place. If pliers did not reduce the distance between the electrodes accordingly, empty spaces would be engendered between electrodes and metal. In order to continue to flow within the discharge loop, power would form archs of current, thus causing sparks.

As prevoiusly said, such risk is minimized by the pliers capability to apply a strong pressure between the metals constantly, also during the welding phase. However, the clinician is asked to verify that mucous membranes, soft tissues or suture threads do not come between metals and electrodes.

Another parameter to take into consideration is the choice of proper welding parameters. Higher power levels, passed through thin metals, could cause the whole metal to be fused instead of welded, thus resulting in the metal split and spattering of fused metal pieces within the oral cavity.

The choice of the welding parameters is simplified by using the pre-installed programs. However, the clinician is asked to make some extra-oral welding test in order to select the parameters the most appropriate to the kind of implant and bar used.

Labels

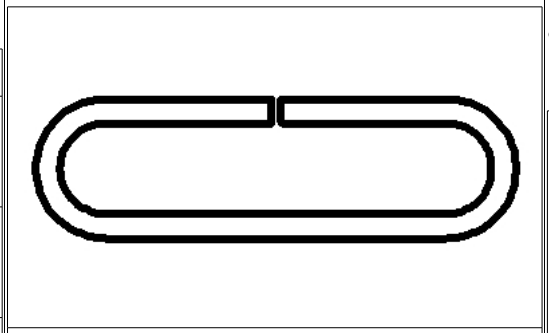
Permanently attached to the product or its

wrapping are the following labels, clearly visible during working, maitenance and assitance of the equipment.

S&W	Company Logo
REF	Product model PAPINEWD001.1
LOT	Production batch number
135°C	Sterilization requirements: Steam sterilization 135°C for 20 minutes
	Indication of general risk and reference to the user's manual
	Indication of the Applied Part Class: Type BF
CE 0476	The CE mark is applied on the product in conformity with the European directives and the appliable standards, in particular: - directive 93/42/CE, L.D. 46/90 - regulation CEI EN 60601-1:1998

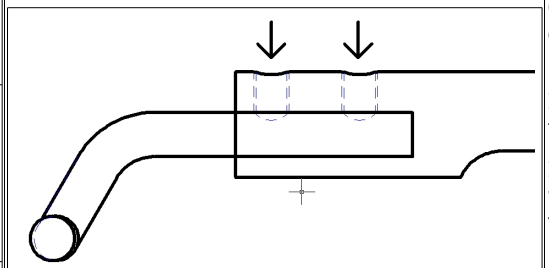
Sterilization

Press the pliers handles till they are near enough to apply the fixing ring shown in pict.1 on the lower side.



Pict.1 Fixing ring

Using the supplied hexagonal key, loosen the four screws (two on both sides) that hold the electrodes in their welding position (see pict.2)



Pict. 2 Electrodes takedown

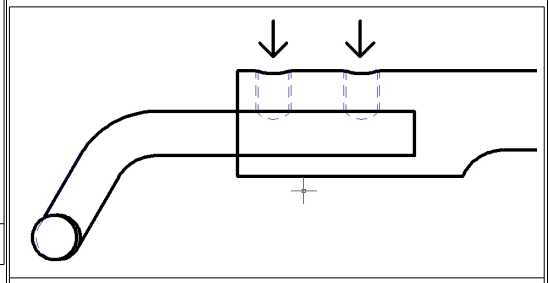
Draw the electrodes out and put them in the bag for the steam sterilization, seal and put it in the autoclave with the hexagonal key.

Place the pliers in another bag, seal and put it in the autoclave.

Start the sterilization cycle at 135°C for 20 minutes.

Set up for use

Take pliers and electrodes from the sterilization bags. In order not to contaminate the items, use sterile gloves and handle the products cautiously. The two copper electrodes have to be embedded as shown in pict. 3 and tightly fixed on the sites indicated by the arrows using the supplied hexagonal key:



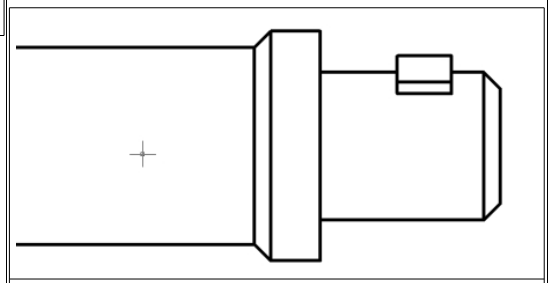
Pict.3 Electrodes fixing

Remove the fixing ring applied on the lower side pressing slightly on the pliers handles.

Once the pliers handles have been released, check that the electrodes faces be placed in parallel one in front of the other.

In case it does not occur, repeat the procedure to fix the screws.

Insert the cables connectors coming from the welder station into the connectors situated in the lower part of the pliers (see pict.4)



Pict. 4 Pliers connector

Maintenaince

PEWD intra-oral pliers do not need special maintenance.

They can be cleaned with ordinary detergents.

Before and after any use, as well as after any sterilization, check that the product has not undergone significant changes in its shape, color and opening and closing technical capacity. In particular, verify that the electrodes close properly one in front of the other and are tightly screw-fixed. Otherwise, screw them in.

The pliers and electrodes conditions can affect the welding quality. For this reason they must be attentively checked.

Using particularly worn electrodes can engender sparks formation within the oral cavity during the welding phase, thus exposing the patient to the risk of being burned. Such a danger is practically erased by using new electrodes.

Whenever pliers or electrodes show signs of wear, they must be replaced.